REMARKS

Reconsideration of the above-referenced patent application is respectfully requested in view of the foregoing amendments and remarks set forth herein.

New claim 11 recites: A method of producing a product for improving immune-function in mammals, comprising:

a. determining the cytotoxic activity of strains of *Lactobacillus reuteri* by evaluating supernatants for good toxin binding and a toxin neutralizing effect, said supernatants obtained from growing each strain of *Lactobacillus reuteri* in suitable host cells,
b. selecting strains of *Lactobacillus reuteri* having a good toxin binding and toxin neutralizing effect,
c. testing cells of the selected strains of *Lactobacillus reuteri* for immunomodulating activity by testing for an increase in the number of CD4+ lymphocytes in tissue samples from a test mammal to which the strains have been administered, and
d. formulating the product to contain cells of a strain of *Lactobacillus reuteri* having an increase in the number of CD4+ lymphocytes in the samples from the test mammal.

Support for this terminology is found in claim 10 previously submitted for which support was found in original claim 1, and at paragraphs [0027] and [0041] and the examples of the published application.

New claim 12 recites: A product comprising the culture supernatant of *Lactobacillus reuteri* strain ATCC55730 having the capability of increasing the number of CD4+ lymphocytes and has good toxin binding and a good toxin neutralizing effect when administered to a mammal. Support for this terminology is found in claim 8 as originally filed.

In the Office Action of **March 31, 2009**, the Examiner took the following actions to which Applicant herein makes response: (1) rejected claims 2-7 and 10 Section 112, second paragraph as being indefinite, stating that the step of "selecting and culturing" is

indefinite, "a substance" is not described, there are confusing and inconsistent steps (10d), there is an overall lack of clear and distinct recitation of process; claim 2 is unclear as to what characteristics are to be in claim 2, "strain capability" lacks antecedent basis in claim 10, and "samples from test mammal" are indefinite ; (2) rejected claims 2-7 under Section 102(b) as being anticipated by, or in the alternative under Section 103(a) as obvious over, newly cited Cavadini (5,968,569); (3) provisionally rejected claims 2-5 and 7 under the ground of nonstatutory obviousness-type double patenting over claims 1-2, 5 and 6 of copending SN 11/123,330; and (4) stated that claim 10 was rendered free of the prior art. These rejections are traversed in application to the claims as amended, and consideration is requested of the patentability of claims 2-7 and 11-12 now pending in the application.

(1) Rejection of claims 2-7 and 10 Section 112, second paragraph as being indefinite, stating that the step of "selecting and culturing" is indefinite, "a substance" is not described, there are confusing and inconsistent steps (10d), there is an overall lack of clear and distinct recitation of process; claim 2 is unclear as to what characteristics are to be in claim 2, "strain capability" lacks antecedent basis in claim 10, and "samples from test mammal" are indefinite

Applicant has replaced claim 10 by new claim 11. In a telephone conference initiated by the undersigned attorney, a slightly different version of new claim 11 was discussed. A number of remaining issues with the proposed claim 11 were discussed. Applicant in the herein submitted new claim 11 language has attempted to address any remaining problems with claim 11. Thus, Applicant has clarified the supernatant terminology (discussed in the telephone conference) to recite: "said supernatants obtained from growing each strain of *Lactobacillus reuteri* in suitable host cells". Applicant requests the Examiner to take judicial notice that growing microbial cells in host cells, and determining suitable host cells for such growth are well known in the art. Further, the terms "selecting and culturing", "strain capability" and "a substance" no longer appear in new claim 11. Also, Applicant has specified that the samples from the mammals are

tissue samples. One of ordinary skill in the art knows which tissues to sample, and how to sample the tissues for the number of CD4+ lymphocytes.

Applicant respectfully submits that the steps of new claim 11 are clear and distinct; however, if the Examiner has suggested changes to place claim 11 in better form, Applicant would be pleased to consider making such changes.

Applicant respectfully submits that new claim 11 (replacing claim 10) and claims 2-7, which depend therefrom, are patentable under Section 112, second paragraph.

(2) Rejection of claims 2-7 under Section 102(b) as being anticipated by, or in the alternative under Section 103(a) as obvious over, newly cited Cavadini (5,968,569)

Applicant respectfully submits that Cavadini neither teaches nor suggests Applicant's invention according to new claim 11 herein. In particular, Cavadini neither teaches nor suggests selecting a strain with the characteristics set forth in claim 11, in which "the strain has the capability of increasing the number of CD4+ lymphocytes and has good toxin binding and a good toxin neutralizing effect when administered to a mammal". While Cavadini may use strains of *L. reuteri*, Applicant submits that there is nothing in Cavadini to suggest that the strains have these characteristics. In other words, it would be a matter of random chance whether such a strain were used by Cavadini, whereas in Applicant's product a strain with such characteristics **is used,** no doubts or random chances. These characteristics are *not* necessarily inherent in the strains used by Cavadini or by anyone else, and unless there has been a selection as set forth and claimed by Applicant, a product formulated with *L. reuteri* strains not specifically so selected more likely than not *do not* have these characteristics.

Applicant therefore submits that claims 2-7 for a product comprising a "strain [that] has the capability of increasing the number of CD4+ lymphocytes and has good toxin binding and a good toxin neutralizing effect when administered to a mammal" are allowable under Sections 102(b) and 103(a) over Cavadini.

(3) Provisional rejection of claims 2-5 and 7 under the ground of nonstatutory

obviousness-type double patenting over claims 1-2, 5 and 6 of copending SN 11/123,330 (client file: BIOA5110)

Applicant respectfully submits that claim 1 of copending SN 11/123,330 is for "A liquid oil-based product for improved immune function in mammals, including humans, comprising 3-HPA producing lactic acid bacteria suspended in a medium chain triglyceride oil" and that the other cited claims of the copending application depend from and contain all of the limitations of claim 1 of the copending application. Applicant respectfully submits that there are many types of processes that improve immune function and that lactic acid bacteria that are selected because they produce 3-HPA and lactic acid bacteria that are selected because they have good toxin binding and a toxin neutralizing effect and further cause an increase in the number of CD4+ lymphocytes in samples from a test mammal are not necessarily, or even likely, to be the same strains. These are two different sets of physiological and biochemical criteria, neither of which has been previously used in the manner of these two inventions, and neither of which is an obvious characteristic of a microbial species in view of the other characteristic.

Applicant therefore submits that even if copending SN 11/123,330 and the rejected claims herein are patented, there would be no obviousness-type double patenting.

(4) Statement that claim 10 was rendered free of the prior art

Applicant respectfully submits that claim 11, replacing claim 10, remains free of the prior art, and is allowable condition.

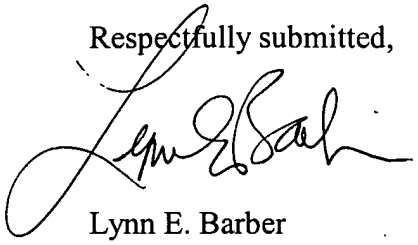
Conclusion

For all the foregoing reasons, claims 2-7 and 11-12 are submitted to be fully patentably distinguished over the cited references and in allowable condition. Favorable consideration is therefore requested.

Applicant submits that no new claims have been added and therefore that no fee is required for the presentation of this amendment except for the separately submitted fee for extension of time. Any additional amounts that may be due for presentation of this amendment should be charged to Deposit Account No. 02-0825 of Applicant's attorney.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a personal or telephonic conference with Applicant's attorney, the Examiner is invited to contact such attorney at the telephone number noted below.

Respectfully submitted,



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